DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 12, 2015

Interojo Inc.
Mr. Bret Andre
Official Correspondent
EyeReg Consulting, Inc.
474 NE 61st PL
Hillsboro, Oregon 97124

Re: K142766
Trade/Device Name: I-55 (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear (clear and tinted, fully cast-molded)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 5, 2015
Received: February 12, 2015

Dear Mr. Andre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, MD
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142766

Device Name
I-55 (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear (clear and tinted, fully cast-molded)

Indications for Use *(Describe)*
The I-55 (methafilcon A) Spherical Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The I-55 (methafilcon A) Toric Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The I-55 (methafilcon A) Multifocal Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The I-55 (methafilcon A) Toric-Multifocal Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia, possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for single use Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lens is to be discarded after each removal.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K142766

Applicant information:

Date Prepared:	September 23rd, 2014
Name:	**Interojo, Inc.** #803, Yulchon B/D, 24-1, Youidong, Youngpodong, Seoul, South Korea
Contact Person:	Si-Chul Rho President
Phone number:	+82-2-780-1225
Consultant:	Bret J Andre EyeReg Consulting, Inc. 474 NE 61st Pl Hillsboro, OR 97124 United States
Phone number:	(503) 372-5226

Device Information:

Device Classification:	Class II
Product Code:	LPL; MVN
Classification Name:	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Trade Name:	**I-55 (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear (clear and tinted, fully cast-molded)**

Equivalent Devices:

The **I-55** (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear (clear and tinted, fully cast-molded) are substantially equivalent to the following predicate devices:

Predicate devices:

- **"I-55 (methafilcon A)"**
  By PolyVue Distribution, Inc.
  510(k) number; K080794
  -Primary Predicate

- **"HD/HDT, PV/PVT (polymacon)"**
  By PolyVue Technologies, Inc.
  510(k) number; K013220

Device Description:

The **I-55** soft contact lenses are hemispherical shells with molded spherical base curves and molded front surfaces.

The nonionic lens material (methafilcon A) is a hydrophilic co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and methacrylic acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in saline solution. The (methafilcon A) name has been adopted by the United States Adopted Names Council (USAN).

I-55 lenses are available clear, visibility tinted (for handling), and tinted to enhance or alter the apparent color of the eye. Lenses are tinted with one or a combination of one or more of the following 'listed' color additives:

Name of Colorant	Listing
[Phthalocyaninato(2-)] copper	21 CFR § 74.3045
D&C Green No.6	21 CFR § 74.3206
D&C Red No.17	21 CFR § 74.3230
D&C Violet No.2	21 CFR § 74.3602
D&C Yellow No.10	21 CFR § 74.3710
Titanium dioxide	21 CFR § 73.3126

Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect. When producing the tinted lenses, the manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed reactive color additive(s) on the front surface of the contact lens in a location that corresponds to the iris. As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound color additives. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens in the location that corresponds to the iris, the coloring process does not alter the original characteristics of the pre-tinted lens. The tinting pattern has a standard

Clear Pupil diameter of 6.5 mm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (methafilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the lens are:

Refractive Index	1.415
Light Transmission (clear)	greater than 90%
Light Transmission (tinted)	greater than 90%
Surface Character	hydrophilic
Water Content	55±2%
Specific Gravity	1.039 (hydrated)
Oxygen Permeability	19.01×10^{-11} $(cm^2/sec)(mlO_2)/(ml \times hPa @ 35°C)$ (revised Fatt method)

The hydrophilic characteristics allow aqueous solution to enter the lens, and in its fully hydrated state the lens is approximately 38% water by weight. The lenses will be manufactured in the sphere, toric, multifocal, and toric multifocal design configurations with the following features and properties:

Chord Diameter:	13.00 mm to 15.00 mm
Center Thickness:	0.080 mm to 0.580 mm
Base Curve:	8.0 mm to 9.8 mm
Power Range	
- Sphere Power:	-12.00D to +12.00D in 0.25D steps
- Cylinder Power (toric):	-0.25D to -2.25D in 0.25D steps
- Cylinder Axis (toric):	10° to 180° in 10° steps
- Multifocal Power:	+1.25 to +2.50 in 0.25D steps

Intended Use:

The **I-55 (methafilcon A) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **I-55 (methafilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **I-55 (methafilcon A) Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

The **I-55 (methafilcon A) Toric-Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia, possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for single use Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lens is to be discarded after each removal.

Pre-Clinical Performance Data:

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **I-55** soft contact lenses—including listed color additives. All non-clinical toxicology tests were conducted in accordance with the GLP regulation.

Test results of the non-clinical testing on the **I-55** soft contact lenses demonstrate that:

- The parameters of finished contact lenses with listed color additives remain stable for proposed expiration date.
- The finished contact lenses with color additives, packaging material and extracts are not toxic and not irritating.
- The finished contact lenses with color additives remain within original specifications.

Pre-clinical performance data established by the I-55 predicate device (K080794) include:

- Data establishing the consistency of the physical and material properties between the I-55 soft contact lenses and other currently marketed lenses.

- Data establishing the sterility of finished lenses supplied in specified packaging for the indicated shelf-life.
- Biocompatibilty data to establish that the packaging material and extracts are not toxic and not irritating.
- All relevant manufacturing/chemistry data, including verification data.

Substantial Equivalence:

The **I-55** Soft Contact Lens will be manufactured according to specified process controls and a cGMP quality assurance program currently in place as established by the I-55 predicate device (K080794)**.**

The final packaging and sterilization of the **I-55** lenses will be carried out in accordance with procedures specified for the I-55 predicate device (K080794).

The **I-55** Soft Contact Lenses are manufactured using the identical process to incorporate the listed color additives in the contact lenses as the HD/HDT, PV/PVT (polymacon) reference predicate device (K013220).

The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the **I-55** contact lens material is equivalent to the predicate devices identified previously. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and ***does not raise*** different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates the equivalencies of the **I-55** (methafilcon A) Soft Contact Lenses for Daily Wear, as well as the substantial equivalent predicate devices.

Substantial Equivalence Matrix

	Interojo, Inc. I-55 Subject Device	**PolyVue Distribution, Inc. I-55 Predicate Device**	**PolyVue Technologies, Inc. HD/HDT, PV/PVT Predicate Device**
Intended Use	Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 Diopters, and/or are presbyopic. The lens may be used to enhance or alter the apparent color of the eye.	Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 Diopters, and/or are presbyopic.	Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 Diopters, and/or are presbyopic. The lens may be used to enhance or alter the apparent color of the eye.
Functionality	Same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Indications	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
Production Method	Fully-molded	Fully-molded	Fully-molded
USAN name	methafilcon A	methafilcon A	polymacon
Water Content (%)	55±2%	55±2%	38±2%
Oxygen Permeability	19.01×10^{-11} $(cm^2/sec)(ml O_2)/(ml \times hPa @ 35°C))$ (revised Fatt method)	19.01×10^{-11} $(cm^2/sec)(ml O_2)/(ml \times hPa @ 35°C))$ (revised Fatt method)	8.40×10^{-11} $(cm^2/sec)(ml O_2)/(ml \times hPa @ 35°C))$ (revised Fatt method
Specific Gravity	1.039 (hydrated)	1.039 (hydrated)	-